IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO

PHYSICIANS OF WINTER HAVEN LLC D/B/A DAY SURGERY CENTER, on behalf of itself and all others similarly situated,	)	Case No.:
	)	Judge:
Plaintiff,	)	CLASS ACTION COMPLAINT
v.	)	JURY TRIAL DEMANDED
STERIS CORPORATION,	)	
Defendant.	)	

Plaintiff PHYSICIANS OF WINTER HAVEN, LLC, D/B/A DAY SURGERY CENTER ("Plaintiff"), by and through its attorneys, individually and on behalf of all others similarly situated, alleges as follows upon personal knowledge as to itself, and as to all other matters upon information and belief, and based upon the investigation undertaken by its counsel:

NATURE OF THE CASE

1. This is a class action lawsuit brought against Defendant Steris Corporation ("Steris" or "Defendant") by Plaintiff on behalf of itself and on behalf of all other similarly situated purchasers of STERIS System 1 Processors (the "Steris System") which have not been approved by the Food and Drug Administration ("FDA").

2. The Steris System is a tabletop liquid chemical system that Defendant promotes for the purpose of sterilizing and disinfecting surgical instruments (such as

endoscopes and bronchoscopes). Sterilization and disinfection systems such as the Steris System are used by hospitals, surgery centers, and other healthcare providers to destroy potentially dangerous microorganisms that could cause infections if left on medical devices.

3. Sterilization systems such as the Steris System must be submitted to the FDA pursuant to the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.,* before they can be sold to healthcare providers. Manufacturers that wish to sell such devices must file a premarket notification with the FDA pursuant to 21 U.S.C. § 360(k) (a "premarket notice" or "510(k) notice").

4. In 1989, the FDA approved the sale of a Steris device called the "Steris System I Processor and Sterilant 20," pursuant to a premarket notice filed by Defendant. Subsequent to the FDA's approval of this device, Defendant made several material alterations to the design of the Steris System I Processor and Sterilant 20. Upon information and belief, these changes were made by Defendant at various points between 1988 and 2002.

5. Defendant's changes to the Steris System I Processor and Sterilant 20 were so substantial that, according to the FDA, each one of them would require the filing of a new premarket notification with the agency.

6. Defendant failed to file premarket notifications with the FDA in connection with any of these changes. In May of 2008, the FDA sent Defendant a Warning Letter because it had failed to file the requisite premarket notifications with the FDA. The Warning Letter advised Defendant that these changes made between

1988 and 2002 could significantly affect the safety and effectiveness of the Steris System.

7. Defendant failed to adequately respond to the FDA's Warning Letter. Consequently, in December of 2009, the FDA sent "Dear Healthcare Facility Administrator and Infection Control Practitioner" letters to Steris System owners. This letter warned owners of the Steris System that the FDA had not approved or cleared the modified Steris System. It also referred to reports of "malfunctions" that had the potential to cause infections to patients, and of burns from exposure to the solution in the Steris System by healthcare operators. The FDA recommended that recipients of the letter "transition" to alternative sterilizers "as soon as possible to ensure continued patient safety."

8. Defendant has and continues to deny that the FDA's position is meritorious. On January 20, 2009, it sent form letters out to its "valued" Steris System customers. Among other things, this letter announced that Steris had submitted a new premarket notice on January 5, 2009 in connection with a new, "updated" Steris System; it would discontinue sales of the Steris System that is the subject of the FDA Warning Letter (and this action); and will continue to support existing Steris Systems "for at least two years." Significantly, Defendant did not offer to allow Class members to return their defective Steris Systems for a refund; instead, it simply stated that Steris "will work with customers on a timetable to transition to the purchase of a replacement for its System 1 product." The letter also provides a hotline that customers can call to report a "serious adverse event."

9. The FDA has publically criticized Steris' handling of the unapproved Steris Systems, stating that it is "not satisfied that [Steris] has been working efficiently to transition its customers to replacements for the [Steris System.]."

10. On February 2, 2010 the FDA issued a supplemental "Dear Healthcare Facility Administrator and Infection Control Practitioner" letter to Class members which updated its previous correspondence from December 2009. In this letter, the FDA stated in unequivocal terms that "Steris Corporation has chosen not to seek FDA clearance of this device and, therefore, its use should be discontinued as soon as practicable." (emphasis supplied).

11. Steris' failure to submit a proper premarket notification to the FDA before selling the modified Steris System is not a technical or trivial violation of the FDCA. Indeed, the FDA has cautioned healthcare providers as follows:

> **What risks are associated with the use of an unapproved or uncleared medical device? Are patients at risk if I use this device?**
>
> Use of a device that is promoted to sterilize or disinfect a medical or surgical device, but that does not properly perform these functions, poses risks to patients and device users. Improperly disinfected or sterilized instruments may transmit pathogens to patients and users, or expose them to hazardous chemicals. Improper sterilization or disinfection may also adversely affect the quality and functionality of reprocessed instruments.

12. As set forth below, Defendant's efforts to remedy its sale of the non-FDA approved and potentially dangerous Steris Systems have been wholly inadequate, and its conduct constitutes an unfair trade practice, breach of warranties, and violations of other state laws. Plaintiff, on behalf of itself and on behalf of the Class defined herein, seeks monetary damages, injunctive relief,

attorneys' fees, and costs against Defendant for damages caused as a proximate result of their purchase of the Steris System. In particular, Plaintiff seeks, *inter alia*, an order requiring Defendant to repair or replace the Steris Systems with comparable sterilizers that actually have the appropriate FDA approval, and/or offer a refund to class members who purchased the Defendant's Steris Systems products.

JURISDICTION AND VENUE

13. This Court has subject matter jurisdiction pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d)(2), because: (i) there are 100 or more class members, (ii) there is an aggregate amount in controversy of at least $5,000,000, exclusive of interest and costs, and (iii) there is minimal diversity because at least one plaintiff and one defendant are citizens of different states. This Court has over supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367.

14. This Court has personal jurisdiction over Defendant because it transacts substantial business in Ohio and in this Judicial District. Defendant is an Ohio corporation, is headquartered in Ohio, and sells its Steris Systems and other products throughout the State of Ohio.

15. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(a)(2) because a substantial part of the events or omissions giving rise to the claims asserted herein occurred in this Judicial District, and because Steris resides in this Judicial District.

THE PARTIES

The Plaintiff

16. Plaintiff PHYSICIANS OF WINTER HAVEN, LLC, D/B/A DAY SURGERY CENTER maintains its headquarters at 2400 Dundee Road in Winter Haven, Florida, and specializes in outpatient surgery. In or around 2005, Plaintiff purchased two Steris Systems from Defendant. As a result of Defendant's misconduct, members of Plaintiff's staff regularly spend extra time and resources to perform biological tests on its Steris Systems to ensure that it is working properly. Plaintiff has also been injured because the price it paid for the Steris Systems was artificially inflated as a result of Defendant's misstatements, omissions and misconduct, and because Plaintiff must now purchase a replacement sterilization device.

The Defendant

17. Defendant Steris Corporation is an Ohio corporation that maintains its principal place of business at 5960 Heisley Road in Mentor, Ohio. Steris issues securities that are publicly traded on the New York Stock Exchange under the ticker symbol "STE." In its most recent Form 10-K filed with the Securities and Exchange Commission ("SEC"), Steris recognized in excess of $1.2 billion in annual revenue, and a gross profit of over $526 million during that period.

FACTUAL ALLEGATIONS

A. Steris and the Steris System.

18. In its 2009 Form 10-K, Steris describes itself as "a leading provider of infection prevention and surgical products and services, focused primarily on the critical markets of healthcare, pharmaceutical and research." Among other products, Steris sells sterilizers and surgical tables; consumable products, such as detergents and skin care products; and services, including equipment installation and maintenance; as well as the bulk sterilization of single-use medical devices.

19. Upon information and belief, Steris did not disclose to Plaintiff and Class members that its Steris System was not approved by the FDA when it was sold to them. Steris also has made numerous affirmative representations concerning the high quality and efficiency of the modified Steris System. For example, the following claims are made by Steris in the Operator Manual for the Steris System 1 Processor:

a. "Devices approved by STERIS that are processed in the [Steris System] will be sterile and ready for immediate use in patient procedures."

b. "The STERIS PROCESS™ employs the STERIS SYSTEM 1™ Processor, specialized JIT™ Processing Trays and Containers, and STERIS sterilant for the rapid, safe and standardized sterile processing of immersible surgical and diagnostic devices."

c. "The Processor is an automated, microcomputer controlled device which maintains the process parameters necessary to ensure standardized and effective sterile processing."

d. The "STERIS PROCESS™ STERILIZATION GUARNTEE" which guarantees, *inter alia,* that "[t]he STERIS PROCESS will sterilize immersible surgical and diagnostic devices and rinse the devices with sterile water."

e. "Devices are sterilized, rinsed, and ready for immediate use upon the successful completion of the sterile processing cycle…"

B. FDCA Approval Requirements for Sterilization Devices.

20. The Steris System is a "device" within the meaning of the FDCA. Section 510(k) of the FDCA requires device manufacturers who must register, to notify FDA of their intent to market a medical device at least 90 days in advance. The FDA has an important gate-keeping function to ensure that only safe sterilizers are made available for use.

21. In light of these requirements, Defendant initially applied for and received FDA clearance in 1989 for a previous design of the Steris System.

22. Subsequent to receiving FDA clearance in 1989, Defendant made several changes to the Steris System that necessitated the filing of new premarket notifications with the FDA.

C. The May 2008 Warning Letter to Steris.

23. Specifically, on May 15, 2008, the District Director for the Cincinnati District of the FDA sent a Warning Letter to Walter M. Rosebrough (the president and CEO of Steris) that identified six separate changes to different components in the Steris System made by Defendant:

a. **Changes to the Circulation Pump.** In 1999, Defendant changed the design of a circulation pump in the Steris System which, altered the flow rate, the now characteristics, and the flow through the lumen of the device. According to the FDA, these changes significantly impacted the function and delivery of the sterilant to and through the Steris System.

b. **Changes to the High Pressure Pump.** Between 1992 and 1999, Defendant made changes to the high pressure pump in the Steris System that changed the flow rate, and installed pressure switches to monitor the function of the high pressure pump. According to the FDA, these pump changes significantly impact the function and delivery of the sterilant to and through the Steris System.

c. **Software Changes.** In 1996, Defendant changed the original software in the Steris System (which had been cleared by the FDA in 1989) to limit the operation of the high pressure pump to the sterilant exposure phase and the final drain. Because of this software change, the high pressure pump no longer runs during the final rinse phase. According to the FDA, this action may affect removal of chemical residues from the processed devices and "may pose a risk to the patient."

d. **Connector Design Changes.** In or around 2002, Defendant changed the connector design on the Quick Connect Kits from individual components to one unit, in which all of the components are tethered together. Additionally, new connectors were developed to facilitate the adaptation

of the flow unit to the instrument to be processed. According to the FDA, these changes to the connectors have a significant effect on the sterile fluid pathway and delivery of the sterilant.

e. **Changes to the Chamber Volume.** Defendant substantially increased the size of the chamber volume from the volume amount approved by the FDA. According to the FDA, this large increase in chamber volume, which apparently also prompted a change in sterilant formulation, "could significantly affect the ability of the system to sterilize by altering how sterilant is delivered and the concentration of ingredients in the sterilant."

f. **Additional Ingredients to the Sterilizing Fluid.** Subsequent to FDA approval of the Steris System, Defendant added five additional ingredients to (and changed the formulation of) Sterilant 20. Sterilant 20 is the chemical that is used to sanitize instruments put into the Steris System. According to the FDA, these changes to Sterilant 20 "could significantly affect safety or effectiveness of the device, specifically, the effectiveness of the active ingredient and its ability to sterilize, and by altering the stability of the sterilant."

24. The FDA's Warning Letter states that each of these changes "could significantly affect the safety or effectiveness" of the Steris System, and that any of these six changes would, in and of itself, trigger the requirement that a new premarket authorization be submitted to the FDA.

25. The FDA also identified additional changes made by Defendant to the design of the Steris System, which "cumulatively result in a change in the overall device design that could significantly affect safety and effectiveness."

26. Based on the FDA's investigation into Steris' changes to the Steris System, it concluded (and advised Rosebrough):

> your device is adulterated under [the FDCA] because you do not have an approved application for premarket approval…in effect pursuant to [the FDCA], or an approved application for an investigational device exemption (IDE) under [the FDCA]. The device is also misbranded under [the FDCA], because you did not notify the agency of your intent to introduce the device into commercial distribution, as required by section 510(k) of the [the FDCA].

27. The FDA letter told Rosebrough that Steris "should take prompt action to correct the violations addressed in this letter."

28. According to its most recent Form 10-K filed with the SEC, Steris responded to the FDA's Warning Letter in July of 2008. Steris' position was "that the assertions in the warning letter are not correct."

29. The FDA responded to Steris' letter on or around November 4, 2008. According to Steris, the FDA stated "that, after reviewing [Steris'] response, it disagreed with our position and that a new premarket notification submission is required."

D. Defendant's January 2009 Letter to Class Members.

30. On or around January 20, 2009, Steris sent letters to its customers regarding the FDA's May 2008 Warning Letter. In this letter, Steris claimed to

have submitted a new premarket notification to the FDA on January 5, 2009 for "an updated STERIS System 1."

31. Significantly, the submission of this new premarket notification with respect to the updated STERIS System 1 does nothing to benefit Plaintiff and similarly situated Class members that purchased the original STERIS System 1 Processor. With respect to those original models, Steris stated that it was discontinuing their sale in the United States, with the exception of sales related to "product replacement."

32. Steris said that it would "continue to support existing System 1 Processors for at least two years from the date of this notice." According to Steris, this support includes "selling replacement units on a one-for-one basis."

E. The FDA's December 2009 Notice to Healthcare Providers.

33. Dissatisfied with Steris' response (or lack thereof) to its May 2008 Warning Letter, on December 3, 2009 the FDA took the initiative to contact healthcare facilities that owned or operated a Steris System.

34. The FDA's December 2009 communication reiterated that it had not approved the modified Steris System, and that continuing to use it without this approval could pose risks to patients and users:

> [Steris] has significantly modified the [Steris System], and FDA has not approved or cleared this modified product. Thus, FDA has not determined whether the [Steris System], is safe or effective for its labeled claims, including claims that it sterilizes medical devices. Use of a device that is promoted to sterilize or disinfect a medical or surgical device, but that does not properly perform these functions, poses risks to patients and users. Improperly disinfected or sterilized instruments may transmit pathogens to patients and healthcare staff,

> or expose them to hazardous chemicals. Improper sterilization or disinfection may also adversely affect the quality and functionality of reprocessed instruments.

35. The FDA also reported that it had "received some reports of malfunctions of the [Steris System] that had the potential to cause or contribute to serious injuries to patients, such as infections." In addition, the FDA cited "reports of injuries, mostly burns from exposure to the sterilant solution, to healthcare facility staff operating the device."

36. The FDA notice also discussed Steris' response to its May 2008 Warning Letter. According to the FDA, Steris had "stated that it would work with its customers to transition them to legally-marketed replacements for the [Steris System." Significantly, however, the FDA was not satisfied with this transition: "based on a recent inspection of STERIS and meetings with the firm, FDA is not satisfied that the firm has been working effectively to transition its customers to replacements for the [Steris System]."

37. The FDA concluded its notice to healthcare providers with the following recommendation:

> If you have an acceptable alternative to the [Steris System] to meet your sterilization and disinfection needs, you should transition to that alternative as soon as possible to ensure continued patient safety. If you do not have an acceptable alternative to the [Steris System], you should promptly assess your facility's patient-care needs and sterilization and disinfection requirements and take steps to obtain legally-marketed substitutes for the [Steris System].

38. The FDA also made available a Questions and Answers webpage related to its investigation of the Steris System. In it, the FDA refers to affirmative misleading statements by Steris related to the Steris System:

> STERIS apparently has been reassuring customers that there is no need for a change in their clinical practice. The firm has also continued to design or redesign new accessories for the [Steris System]. This is inconsistent with commitments made by the firm.

39. The FDA also pointed out that Steris has not recalled the Steris System, but instead has "voluntarily told FDA that it would discontinue U.S. sales of the [Steris System], apart from one-for-one product replacement and support of existing [Steris System] units with accessories, service, and parts, and that it would work with customers on a timetable to replace [Steris System] units in their facilities."

40. Finally, the FDA told healthcare providers that there is "nothing" they could do "to resolve FDA's concerns about the [Steris System]."

41. In response to the FDA's December 3, 2009 Notice, the vice president of technology evaluation and safety at the ECRI Institute (an independent, non-profit organization that researches the best approaches to improving patient care), was reported as saying that "[i]n light of FDA's notice, healthcare facilities have little choice but to discontinue use of the [Steris System] in the coming months."

F. The FDA's December 2009 Conference Calls.

42. On December 4, 2009, the FDA hosted a "key stakeholder conference call" to answer questions by healthcare professionals regarding the Steris System.

According to the transcript of the call, a representative from the FDA stated that the Steris System label claims that the machine is safe and effective.

43. The FDA confirmed on this conference call that the scope of the Steris System units subject to the Warning Letter is very broad. A FDA call representative stated "I'm not aware of any devices out there that would not be subject to the warning letter that was sent to STERIS and the changes that were made by STERIS and therefore subject to our warning letters."

44. On a December 10, 2009 conference call (for which over 1,000 participants had registered), a FDA representative stated that the "FDA believes that healthcare facilities should be able to transition to alternative sterilization and disinfection products in three to six months."

45. With respect to Steris' January 5, 2009 preauthorization application for the new, "updated" Steris model, the FDA representative stated on this call that she could not "assure when or if, or for what scope of use [Steris'] new product will be cleared."

G. Defendant's December 2009 Letters to Class Members.

46. Beginning on or around December 6, 2009, Steris sent another round of letters to its customers. In these letters, Steris claimed to "share your deep commitment to patient safety," and stated that the Steris System 1 processor "has been safely used for more than 300 million cycles over more than 20 years."

47. Steris also claimed that it was "continuing to work" with the FDA to "clarify these issues and develop an efficient transition plan."

H. The FDA's February 2010 Notice to Healthcare Providers.

48. On February 2, 2010, the FDA issued yet another "Dear Healthcare Facility Administrators and Infection Control Practitioners" letter to owners of Steris Systems. For the first time, the FDA clearly and unequivocally stated that hospitals and healthcare facilities should promptly stop using their Steris Systems:

> As FDA announced in its December 3, 2009, notice, the Agency has not approved or cleared the [Steris System] for its labeled claims. Steris Corporation has chosen not to seek FDA clearance of this device and, therefore, its use should be discontinued as soon as practicable.

49. The FDA also extended the recommended transition period for switching from the Steris System to a legally-marketed device to 18 months (from three to six months). The February 2010 FDA letter explained that the reason for this expanded recommended transition time was because the three to six month period "may present significant difficulties for some healthcare facilities, which could, in turn, adversely affect patient care."

50. The FDA stated that it "does not expect to take regulatory action against healthcare facilities for failing to replace [Steris System] units within the 18-month transition period." It did not indicate, however, whether it would take regulatory action against facilities that fail to replace their Steris System during or after the 18 month transition period.

51. Steris responded to this FDA correspondence with a letter of its own dated February 3, 2010. Instead of acknowledging the FDA's recommendation that the use of Steris System "should be discontinued as soon as practicable," Steris

cavalierly indicated that the "FDA also recommends that healthcare facilities continue to transition to alternative reprocessing devices as soon as practicable."

52. As of its February 3, 2010 letter, Steris still had not received approval for the premarket notice it submitted to the FDA with respect to its new, updated Steris System.

I. Defendant's Improper Conduct and Injuries to the Class.

53. Defendant has engaged in improper practices and breached its contracts with Plaintiff and Class members by, *inter alia*, selling Steris Systems that it knew were not approved by the FDA, failing to procure proper FDA approval for the Steris Systems that it sold to Plaintiff and Class members, and shifting the burden of securing a lawful replacement sterilization machine upon Plaintiff and Class members. Upon information and belief, when Defendant sold its Steris Systems to Plaintiff and Class members, it failed to disclose to them that the product was not FDA approved.

54. Defendant could have – but has not – refunded money to Plaintiff and Class members who wish to purchase a lawful replacement sterilization machine. Instead, Defendant is steering them towards purchasing a replacement Steris machine through its "a one-for-one basis" program.

55. Under the circumstances, Plaintiff and Class members should not be coerced into purchasing a replacement Steris machine. As the FDA has recognized, there are several "alternative products" available, such as "FDA-cleared products available to sterilize or disinfect medical devices between patient uses," such as

"liquid chemical sterilant (LCS)/high-level disinfectant (HLD) products that may be used alone or with an automated endoscope reprocessor (AER), or sterilizers for processing (sterilizing or disinfecting) medical devices, including those that employ low-process temperatures." Defendant should not be permitted to generate additional sales revenue as a result of its misconduct.

56. Plaintiff and Class members have been injured because they paid more for the illegal Steris Systems than what they bargained for (*i.e.,* an FDA-approved, lawful sterilization machine). And, as a result of Defendant's misconduct, they must now prematurely (and within a short period of time) stop using Defendant's product and secure (and pay for) a replacement product. But for Defendant's misconduct, Plaintiff and the Class would not incur these costs.

57. Plaintiff and Class members have also been injured because they must devote additional resources to ensure that the Steris Systems are working properly. Moreover, Class members may suffer reputational injuries as a result of patients who may not wish to visit a healthcare facility that has sterilization equipment that has not been approved by the FDA.

58. Under the circumstances, Defendant's attempt to limit the applicable warranties is unconscionable pursuant to OHIO REV. CODE § 1302.15 (U.C.C. § 2-302).

ESTOPPEL FROM RELYING ON THE STATUTE OF LIMITATIONS

59. Defendant is estopped from relying on any statute of limitations by virtue of its acts of fraudulent concealment, which include Defendant's intentional

concealment from Plaintiff and the general public that their Steris System units were defective. Defendant's acts of fraudulent concealment include, without limitation, failing to disclose to purchasers that its Steris System was not approved by the FDA. Through such acts, Defendant was able to conceal from the Plaintiff, members of the Class, and the general public the truth concerning the flaws associated with Steris System.

60. Until shortly before Plaintiff filed this complaint, Plaintiff had no knowledge that Defendant would not satisfactorily remedy its Steris Systems. Plaintiff had no reasonable way to discover the full extent of this defect until shortly before Plaintiff filed this complaint.

CLASS ACTION ALLEGATIONS

61. Plaintiff brings this suit as a class action on behalf of itself and on behalf of all others similarly situated (the "Class") pursuant to FED. R. CIV. P. 23(a), 23(b)(2) and 23(b)(3). Subject to additional information obtained through further investigation and/or discovery, the foregoing definition of the Class may be expanded or narrowed by amendment or amended complaint. Plaintiff seeks to represent the following Class:

> All entities or persons that purchased a Steris System that was not approved by the FDA.

62. This action has been brought and may be properly maintained as a class action for the following reasons:

a. Numerosity: Members of the Class are so numerous that their individual joinder is impracticable. According to Steris, more than 23,000

Steris System units have been used in more than 5,000 hospitals and clinics in the United States since 1988.

b. Existence and Predominance of Commons Questions of Fact and Law: Common questions of law and fact exist as to all members of the Class. These questions predominate over the questions affecting individual Class members. These common legal and factual questions include, but are not limited to, the following:

i. Whether Defendant has violated the Ohio Deceptive Trade Practices Act through its conduct;

ii. Whether Defendant has breach its contract(s) and/or warranties with Plaintiff and members of the Class;

iii. Whether Defendant has been unjustly enriched at the expense of Plaintiff and members of the Class;

iv. Whether Defendant is estopped from relying on the statute of limitations;

v. Whether its warranty limitations are unconscionable;

vi. Whether the defective Steris System should be recalled, repaired, or made FDA-compliant, and whether Defendant should otherwise make Plaintiff and the Class whole; and

vii. Whether Plaintiff and members of the Class have been injured as a result of Defendant's conduct as alleged herein, and, if so,

the extent to which Plaintiff and Class members are entitled to damages and/or other relief.

These and other questions of law or fact which are common to the members of the Class predominate over any questions affecting only individual members of the Class.

c. Typicality: Plaintiff's claims are typical of the claims of the Class since Plaintiff purchased a Steris System that has not been approved by the FDA, just like all members of the Class. Furthermore, Plaintiff and all members of the Class sustained monetary and non-economic injury arising out of Defendant's wrongful conduct. Plaintiff is advancing the same claims and legal theories on behalf of itself and all absent Class members.

d. Adequacy: Plaintiff is an adequate representative of the Class because its interests do not conflict with the interests of the Class that it seek to represent; it has retained counsel competent and highly experienced in complex class action litigation; and it intends to prosecute this action vigorously. The interests of the Class will be fairly and adequately protected by Plaintiff and its counsel.

e. Superiority: A class action is superior to other available means of fair and efficient adjudication of the claims of Plaintiff and members of the Class. The injury suffered by each individual Class member is relatively small in comparison to the burden and expense of individual prosecution of the complex and extensive litigation necessitated by Defendant's conduct. It would be virtually impossible for members of the Class individually to redress effectively the wrongs done to them. Even if the members of the Class could afford such individual litigation, the court system could not.

Individualized litigation presents a potential for inconsistent or contradictory judgments. Further, individualized litigation increases the delay and expense to all parties, and to the court system, presented by the complex legal and factual issues of the case. By contrast, the class action device presents far fewer management difficulties, and provides the benefits of single adjudication, economy of scale, and comprehensive supervision by a single court.

f. Defendant has acted, and has refused to act, on grounds generally applicable to the Class, thereby making appropriate final injunctive relief with respect to the Class as a whole; and

g. In the absence of a class action, Defendant would be unjustly enriched because it would be able to retain the benefits and fruits of its wrongful conduct.

VIOLATIONS ALLEGED

COUNT I
VIOLATIONS OF THE OHIO DECEPTIVE TRADE PRACTICES ACT

63. Plaintiff and the Class incorporate by reference each preceding and succeeding paragraph as though fully set forth at length herein.

64. The Ohio Deceptive Trade Practices Act ("DTPA") is codified at OHIO REV. CODE ANN. § 4165.01, *et seq.* The statute permits a "person" who is injured or who is likely to be injured as a result of a deceptive practice to bring an action under the DTPA. OHIO REV. CODE ANN. § 4165.03(A)(1)-(2).

65. The DTPA defines a "person" broadly to include, *inter alia*, a

corporation, business trust, partnership, unincorporated association, and limited liability company. OHIO REV. CODE ANN. § 4165.01(D). As such, Plaintiff and Class members are "persons" within the meaning of the DTPA.

66. Defendant violated the DTPA by doing the following in the course of its business:

a. Causing a likelihood of confusion or misunderstanding as to the source, sponsorship, approval, or certification of goods;

b. Causing a likelihood of confusion or misunderstanding as to affiliation, connection, or association with, or certification by, another;

c. Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that the person does not have; and

d. Representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another.

67. As a direct and proximate result of Defendant's violations of the CPSA, Plaintiff and members of the Class have been injured.

COUNT II
BREACH OF EXPRESS WARRANTY

68. Plaintiff repeats and incorporates herein by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

69. Defendant expressly warranted to Plaintiff and members of the Class that its Steris System, *inter alia*, would actually work to properly sterilize medical equipment. And by selling the Steris System, Defendant impliedly (if not expressly) warranted that it was lawful.

70. The Steris System does not conform to these express representations because it is not approved by the FDA.

71. As a direct and proximate result of the breach of said warranties, Plaintiff and Class members have been damaged and are therefore entitled to damages.

72. Defendant is estopped from relying on the statute of limitations affirmative defense because it concealed the true nature of its breach of express warranty from Plaintiff and members of the Class.

73. Under Ohio law, every contract has an implied duty of good faith and fair dealing.

74. Steris had a duty to perform its contracts with Plaintiff and Class members related to the Steris System in good faith.

75. Defendant failed to do so, causing injuries to Plaintiff and Class members.

COUNT III
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY

76. Plaintiff repeats and incorporates herein by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

77. Defendant is a "merchant" for purposes of the Uniform Commercial Code.

78. Plaintiff and members of the Class and the Defendant had a valid contract. Pursuant to this contract, Defendant impliedly warranted that the Steris System was merchantable.

79. Defendant breached the implied warranty of merchantability, as the Steris System was not and are not merchantable. Among other infirmities, the Steris System is not fit for the ordinary purposes for which they are used.

80. As a direct and proximate result of the breach of said warranties, Plaintiff and Class members were damaged and are therefore entitled to damages.

81. Under Ohio law, every contract has an implied duty of good faith and fair dealing.

82. Steris had a duty to perform its contracts with Plaintiff and Class members related to the Steris System in good faith.

83. Defendant failed to do so, causing injuries to Plaintiff and Class members.

COUNT IV
BREACH OF THE IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE

84. Plaintiff repeats and incorporates herein by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

85. At the time of contracting, Defendant had reason to know of the Plaintiff's and Class members' particular purpose for purchasing the Steris System

(*i.e.,* sanitizing medical instruments with a machine that has been approved by the FDA).

86. Plaintiff and Class members relied on the Defendant's skill or judgment to select or furnish suitable goods, thereby creating an implied warranty that the goods would be fit for such purpose.

87. The Steris System was not fit for these purposes, thereby causing injuries to Plaintiff and Class members.

88. Under Ohio law, every contract has an implied duty of good faith and fair dealing.

89. Steris had a duty to perform its contracts with Plaintiff and Class members related to the Steris System in good faith.

90. Defendant failed to do so, causing injuries to Plaintiff and Class members.

COUNT V
BREACH OF IMPLIED WARRANTY IN TORT

91. Plaintiff repeats and incorporates herein by reference each and every paragraph of this complaint as though set forth in full in this cause of action

92. There exists a defect in the Steris System (*i.e.,* it is not FDA-approved).

93. This defect was present at the time that the Steris System left the hands and control of Defendant.

94. The injuries suffered by Plaintiff and Class members were directly and proximately caused by the defect.

COUNT VI
TORTIOUS BREACH OF WARRANTY

95. Plaintiff incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

96. Defendant impliedly warranted that the Steris System was of good and merchantable quality—fit and safe for their ordinary intended use.

97. There were design defects in the Steris System manufactured, distributed, and/or sold by Defendant; those Design Defects existed at the time the Machines were sold to the Plaintiff and the other members of the Class; and those Design Defects were the direct and proximate cause of injury to the Plaintiff and the other members of the Class.

98. The fact that the FDA has not approved Defendant's Steris System and has called for hospitals to stop using them render them unfit for their intended purpose.

99. As a direct and proximate result of Defendant's warranty breach, the Plaintiff and the other members of the Class were caused to suffer loss attributable to the decreased value of the product itself, and consequential damages—losses sustained by the purchase of the defective product—and the Plaintiff and the other members of the Class will have to spend monies to repair and/or replace their Steris Systems.

COUNT VII
NEGLIGENT DESIGN AND FAILURE TO WARN

100. Plaintiff incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

101. Defendant knew—or by the exercise of reasonable care should have known—that its Steris System was not approved by the FDA, and that the FDA would make recommendations calling for the Steris Systems to be replaced.

102. Defendant knew that Plaintiff and the other members of the Class—who used Defendant's Steris System for their intended use—were members of a foreseeable class of persons who were and are at risk of suffering serious inconvenience and expense solely because of Defendant's misconduct.

103. At the time Defendant manufactured, distributed, and/or sold the Steris System, it owed a non-delegable duty to persons like the Plaintiff and the other members of the Class to exercise ordinary and reasonable care to obtain FDA approval for them or, at a minimum, to clearly and conspicuously disclose that FDA approval had not been obtained.

104. Defendant failed to exercise reasonable care in obtaining FDA approval for the Steris System.

105. As a direct and proximate result of Defendant's wanton recklessness, carelessness, and negligence, Plaintiff and the other Class members were caused to suffer damages and losses—and the Plaintiff and the other members of the Class will have to spend money to repair and/or replace the defective Steris System.

106. Plaintiff and the other members of the Ohio Class have not committed any contributory negligence.

COUNT VIII
UNJUST ENRICHMENT

107. Plaintiff repeats and incorporates by reference the preceding allegations. This allegation is being plead in the alternative to the contract and warranty claims.

108. Plaintiff and members of the Class conferred a benefit on Defendant by, *inter alia*, purchasing its products.

109. Defendant has retained the monies that it acquired pursuant to the sale of its Steris System to Plaintiff and members of the Class. Defendant knows of and appreciates this benefit.

110. Defendant was and continues to be unjustly enriched at the expense of Plaintiff and Class members. As such, it would be unjust to permit retention of these monies by the Defendant under the circumstances of this case without the payment of restitution to Plaintiff and Class members.

111. Defendant should be required to disgorge this unjust enrichment.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests, on behalf of itself and members of the Class, that this Court:

A. determine that the claims alleged herein may be maintained as a class action under Rule 23(a), (b)(2), and/or (b)(3) of the Federal Rules of Civil Procedure, and issue an order certifying the Class as defined above;

B. award all actual, general, special, punitive, incidental, statutory, and consequential damages to which Plaintiff and Class members are entitled;

C. award pre-judgment and post-judgment interest on such monetary relief;

D. grant appropriate injunctive and/or declaratory relief, including without limitation, an order requiring Defendant to replace, recall, or adequately repair the defective Steris Systems, and/or to require Defendant to take appropriate steps to attempt to secure FDA approval for the Steris Systems;

E. award reasonable attorney's fees and costs; and

F. grant such further and other relief that this Court deems appropriate.

DATED: February 5, 2010.

Respectfully submitted,

/s/ Thomas A. Muzilla

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